ClinicalEvidence

Chronic suppurative otitis media

Search date January 2007

Jose Acuin

ABSTRACT

INTRODUCTION: Chronic suppurative otitis media (CSOM) is a common cause of hearing impairment, disability, and poor scholastic performance, and can occasionally lead to fatal intracranial infections and acute mastoiditis, especially in resource-poor countries. METHODS AND OUTCOMES: We conducted a systematic review and aimed to answer the following clinical questions: What are the effects of treatments for chronic suppurative otitis media in adults; and in children? We searched: Medline, Embase, The Cochrane Library and other important databases up to January 2007 (BMJ Clinical Evidence reviews are updated periodically, please check our website for the most up-to-date version of this review). We included harms alerts from relevant organisations such as the US Food and Drug Administration (FDA) and the UK Medicines and Healthcare products Regulatory Agency (MHRA). RESULTS: We found 48 systematic reviews, RCTs, or observational studies that met our inclusion criteria. We performed a GRADE evaluation of the quality of evidence for interventions. CONCLUSIONS: In this systematic review we present information relating to the effectiveness and safety of the following interventions: ear cleansing, systemic antibiotics, topical antibiotics, topical antiseptics, topical corticosteroids, tympanoplasty (with or without mastoidectomy).

QUESTIONS

INTERVENTIONS

CSOM TREATMENT IN ADULTS

CSOM TREATMENT IN CHILDREN

Covered elsewhere in Clinical Evidence

Acute otitis media

Otitis media with effusion

To be covered in future updates

Management of cholesteatoma

Key points

- Chronic suppurative otitis media (CSOM) causes recurrent or persistent discharge (otorrhoea) through a perforation in the tympanic membrane, and can lead to thickening of the middle ear mucosa, mucosal polyps, and cholesteatoma.

  CSOM is a common cause of hearing impairment, disability, and poor scholastic performance, and can occasionally lead to fatal intracranial infections and acute mastoiditis, especially in resource-poor countries.

- Topical antibiotics either alone or in combination with topical corticosteroids may improve symptoms compared with placebo or either treatment alone in adults, although few adequate studies have been found. There is consensus that topical antibiotics should be combined with ear cleansing.

  We don't know whether topical antiseptics, topical corticosteroids or systemic antibiotics are beneficial in reducing symptoms.

  It is possible that antibiotics against gram negative bacteria may reduce ear discharge more than other classes of antibiotics or placebo.

- We don't know whether tympanoplasty with or without mastoidectomy improves symptoms compared with no surgery or other treatments in adults or children with CSOM.

- In children with CSOM, the benefits of ear cleansing are unknown, although this treatment is usually recommended for children with ear discharge.

We don't know whether topical antiseptics, topical or systemic antibiotics, or topical corticosteroids, alone or in combination with antibiotics, improve symptoms in children with CSOM compared with placebo or other treatments.

It is possible that topical antibiotics improve resolution of ear discharge compared with topical antiseptics, but they may increase the risk of ototoxicity.

DEFINITION

Chronic suppurative otitis media is persistent inflammation of the middle ear or mastoid cavity. Synonyms include "chronic otitis media (without effusion)", chronic mastoiditis, and chronic tympanomastoiditis. Chronic suppurative otitis media is characterised by recurrent or persistent ear discharge (otorrhoea) over 2–6 weeks through a perforation of the tympanic membrane. Typical findings may also include thickened granular middle ear mucosa, mucosal polyps, and cholesteatoma within the middle ear. Chronic suppurative otitis media is differentiated from chronic otitis media with effusion, in which there is an intact tympanic membrane with fluid in the middle ear but no active infection. Chronic suppurative otitis media does not include chronic perforations of the eardrum that are dry, or only occasionally discharge, and have no signs of active infection. Chronic suppurative otitis media with cholesteatoma is not dealt with in this review.

INCIDENCE/ PREVALENCE

The worldwide prevalence of chronic suppurative otitis media is 65–330 million people, and 39–200 million (60%) suffer from clinically significant hearing impairment. [1]

AETIOLOGY/ RISK FACTORS

Chronic suppurative otitis media is assumed to be a complication of acute otitis media, but the risk factors for chronic suppurative otitis media are not clear. Frequent upper respiratory tract infections and poor socioeconomic conditions (overcrowded housing, [2] and poor hygiene and nutrition) may be related to the development of chronic suppurative otitis media. [3] [4] Improvement in housing, hygiene, and nutrition in Maori children was associated with a halving of the prevalence of chronic suppurative otitis media between 1978 and 1987. [5] See also acute otitis media. The most commonly isolated microorganisms are *Pseudomonas aeruginosa* and *Staphylococcus aureus*; [6] *P aeruginosa* has been particularly implicated in the causation of bony necrosis and mucosal disease. However, a systematic review found no clear evidence that antibiotics are effective in preventing the progression of acute to chronic suppurative otitis media even among children who are at high risk for the disease. [7]

PROGNOSIS

The natural history of chronic suppurative otitis media is poorly understood. The perforation may close spontaneously in an unknown portion of cases, but persists in others leading to mild to moderate hearing impairment (about 26–60 dB increase in hearing thresholds), based on surveys among children in Africa, Brazil, [8] India, [9] and Sierra Leone, [10] and among the general population in Thailand. [11] In many resource-poor countries, chronic suppurative otitis media represents the most frequent cause of moderate hearing loss (40–60 dB). [12] Persistent hearing loss during the first 2 years of life may increase learning disabilities and poor scholastic performance. [13] Progressive hearing loss may occur among those in whom infection persists and discharge recurs. Less frequently, spread of infection may lead to life-threatening complications such as intracranial infections and acute mastoiditis. [14] The frequency of serious complications fell from 20% in 1938 to 2.5% in 1948 worldwide and is currently estimated to be about 0.7% to 3.2% worldwide. [6] This is believed to be associated with increased use of antibiotic treatment, tympanoplasty, and mastoidectomy. [15] [16] [17] Otitis media was estimated to have caused 3599 deaths and a loss of almost 1.5 Disability Adjusted Life Years in 2002, 90% of which were in developing countries. [18] Most of these deaths were probably as a result of chronic suppurative otitis media, because acute otitis media is a self-limiting infection (see review on acute otitis media).

AIMS OF INTERVENTION

To improve symptoms of otorrhoea; heal perforations; improve hearing; and reduce complications, with minimum adverse effects of treatment.

OUTCOMES

Dichotomous variables: Proportion of people with otorrhoea measured subjectively or by otoscopy; with tympanic perforation; hearing loss; intra- and extracranial complications; death; or adverse effects. The correlation between subjective cessation of otorrhoea and otoscopic findings was poor in one RCT. [19] Many RCTs used compound outcomes denoting otoscopic activity (that is, otorrhoea or inflammation in the middle ear). **Continuous variables:** Duration of otorrhoea free periods; severity of hearing loss.

METHODS

BMJ Clinical Evidence search and appraisal January 2007. Studies that included both adults (aged greater-than or equal to 16 years) and children (aged less-than or equal to 10 years) or which failed to specify the age of participants were excluded from the benefits section. However, we have included harms data from systematic reviews that included both adults and children. The RCTs varied

in their definitions of chronic suppurative otitis media and measurements of severity. Most RCTs were brief (7 days to 4 weeks). Most had inadequate methods from which to draw reliable conclusions (see main text for descriptions). Participants with cholesteatoma were excluded from most, but not all, trials. All trials excluded people with impending serious complications. The following databases were used to identify studies for this chapter: Medline 1966 to January 2007, Embase 1980 to January 2007, and The Cochrane Database of Systematic Reviews and Cochrane Central Register of Controlled Clinical Trials 2006, Issue 4. Additional searches were carried out using these websites: NHS Centre for Reviews and Dissemination (CRD) — for Database of Abstracts of Reviews of Effects (DARE) and Health Technology Assessment (HTA), Turning Research into Practice (TRIP), and National Institute for Health and Clinical Excellence (NICE). Abstracts of the studies retrieved from the initial search were assessed by an information specialist. Selected studies were then sent to the author for additional assessment, using pre-determined criteria to identify relevant studies. Study design criteria for inclusion in this chapter were: published systematic reviews and RCTs in any language, at least single blinded, and containing more than 20 individuals of whom more than 80% were followed up. There was no minimum length of follow up required to include studies. We excluded all studies described as “open”, “open label”, or not blinded unless blinding was impossible. We also did a search for prospective and retrospective cohort studies for ear cleansing and the surgical interventions. In addition we use a regular surveillance protocol to capture harms alerts from organisations such as the US Food and Drug Administration (FDA) and the UK Medicines and Healthcare products Regulatory Agency (MHRA), which are added to the chapter as required. We have performed a GRADE evaluation of the quality of evidence for interventions included in this review (see table, p 19).

QUESTION What are the effects of treatments for chronic suppurative otitis media in adults?

OPTION ANTIBIOTICS (TOPICAL) PLUS CORTICOSTEROIDS (TOPICAL) IN ADULTS

Reduction in otorrhoea

Compared with placebo Topical antibiotics plus topical corticosteroids (gentamicin plus hydrocortisone) may be more effective at reducing persistent otorrhoea as determined by otoscopy in adults with chronic suppurative otitis media (low-quality evidence).

Compared with topical corticosteroids alone Topical antibiotics plus topical corticosteroids (gentamicin plus hydrocortisone) may be more effective at 3 weeks than the topical corticosteroid betamethasone at reducing the proportion of people with persistent activity on otoscopy (low-quality evidence).

Compared with topical antibiotics alone We don't know whether topical antibiotics plus topical corticosteroids are more effective at increasing clinical response rates in adults with chronic suppurative otitis media (low-quality evidence).

For GRADE evaluation of interventions for chronic suppurative otitis media, see table, p 19 .

Benefits:

Topical antibiotics plus topical corticosteroids versus placebo:
We found two RCTs, which found that topical antibiotics plus corticosteroids significantly reduced persistent otorrhoea compared with placebo (see comment below). [19] [20] The first RCT (123 adults with chronic suppurative otitis media, no cholesteatoma, and no open mastoid cavity) found that significantly fewer people had otoscopically active otitis media after treatment with gentamicin plus hydrocortisone (if compliance to medication was greater than 70%) than after treatment with placebo (appearance of active otitis: 33/64 [52%] people with gentamicin plus hydrocortisone *v* 44/59 [75%] people with placebo; $P < 0.05$). [19] Similar results were found in 42 other people who had an open mastoid cavity. The second RCT (published only as an abstract; 31 adults) also found that gentamicin plus hydrocortisone significantly reduced active otitis media on otoscopy compared with placebo at the end of 4 weeks of treatment (6/17 [35%] with treatment *v* 11/14 [79%] with placebo; OR 0.18, 95% CI 0.05 to 0.75; see comment below). [20]

Topical antibiotics plus topical corticosteroids versus topical corticosteroids alone:
We found one RCT (64 adults), which found that topical gentamicin plus hydrocortisone significantly reduced the proportion of people with persistent activity on otoscopy compared with betamethasone after 3 weeks of treatment (6/30 [20%] with gentamicin–hydrocortisone *v* 17/24 [71%] with betamethasone; RR 0.28, 95% CI 0.13 to 0.60; NNT 2, 95% CI 2 to 4). [21] The RCT did not state whether the assessment of outcomes was double blind and also did not perform an intention to treat analysis.

Topical antibiotics plus topical corticosteroids versus topical antibiotics alone:
We found two RCTs (see table 1, p 18). [22] [23] The RCTs found no clear evidence of a difference between treatments in clinical response. There was only limited data from one RCT, as only the

abstract was reported in English, and it did not state how clinical response or recovery were defined. [22]

Harms:

Topical antibiotics plus topical corticosteroids versus placebo:
One RCT found no increased incidence of tinnitus or vertigo associated with topical gentamicin plus hydrocortisone ear drops. [19] The other RCT did not report adverse effects. [20]

Topical antibiotics plus topical corticosteroids versus topical corticosteroids alone:
The RCT reported one person discontinued treatment with gentamicin plus hydrocortisone drops because of experiencing a burning sensation but no allergic reactions were reported (no further data reported). [21]

Topical antibiotics plus topical corticosteroids versus topical antibiotics alone:
One RCT found deterioration of the audiogram in only one person with topical polymyxin-B plus neomycin plus hydrocortisone after 6–12 days (0/157 [0%] with topical ciprofloxacin *v* 1/138 [0.7%] with topical polymyxin-B plus neomycin plus hydrocortisone; OR 0.12, 95% CI 0.002 to 5.99). [23] The clinical importance of this difference is unclear. It found no significant difference in the proportion of people who had adverse effects between topical ciprofloxacin and topical polymyxin-B plus neomycin plus hydrocortisone (24/165 [15%] with topical ciprofloxacin *v* 12/153 [8%] with topical polymyxin-B plus neomycin plus hydrocortisone; RR 1.86, 95% CI 0.96 to 3.60). [23] Vertigo was reported by two people with topical ciprofloxacin and by none using topical polymyxin-B plus neomycin plus hydrocortisone. Harms were not reported in the English language abstract of a third RCT (see comment). [22]

Comment:

See comment on topical antibiotics, p 7 . There is lack of good evidence to support the benefit of topical antibiotics plus topical corticosteroids with confidence.

OPTION ANTIBIOTICS (SYSTEMIC) IN ADULTS

Reduction in otorrhoea
Compared with topical antibiotics Systemic antibiotics seem to be less effective at reducing persistent otorrhoea at 1−2 weeks in adults (moderate-quality evidence).

Compared with topical antiseptics Oral antibiotics and topical antiseptics seem to be equally effective at reducing the rate of persistent activity on otoscopy (persistent discharge) at 2−4 weeks in adults (moderate-quality evidence).

Compared with each other We don't know which systemic antibiotic is more effective at reducing persistent otorrhoea in adults (low-quality evidence).

Systemic antibiotics added to mastoidectomy or tympanoplasty compared with no antibiotic Preoperative intravenous ceftazidime may be more effective at reducing the proportion of people with otorrhoea on otoscopy at 2 months in adults having mastoidectomy or tympanoplasty (low-quality evidence).

Compared with systemic antibiotics plus topical antibiotics We don't know whether systemic antibiotics alone are more effective at increasing discharge resolution in adults (low-quality evidence).

Note
We found no direct information from RCTs about whether systemic antibiotics are better than no active treatment or no other treatment in adults with chronic suppurative otitis media.

For GRADE evaluation of interventions for chronic suppurative otitis media, see table, p 19 .

Benefits:

Systemic antibiotics versus placebo:
We found no systematic review or RCTs investigating the effects of systemic antibiotics compared with placebo in adults receiving no other treatment.

Systemic antibiotics versus topical antibiotics:
We found one systematic review (Search date 2005) [24] which identified five RCTs in adults (see table 2, p 18). [25] [26] [27] [28] [29] The review found that systemic antibiotics were significantly less effective at reducing persistent otorrhoea compared with topical antibiotics at 1−2 weeks (2 RCTs, 116 people; 37/57 [65%] with systemic non-quinolones *v* 12/59 [20%] with topical quinolones; RR 3.21; 95% CI 1.88 to 5.49). The review also presented the results of the RCTs individually and four of the five RCTs [26] [27] [28] [29] found that topical antibiotics significantly reduced persistent otorrhoea compared with systemic antibiotics (see table 2, p 18 for full results). The topical antibiotics used were ofloxacin, ciprofloxacin, gentamicin, and chloramphenicol. The systemic antibiotics were oral cefalexin, flucloxacillin, cloxacillin, amoxicillin, ciprofloxacin, co-amoxiclav (amoxicillin–clavulanate), and intramuscular gentamicin.

Systemic antibiotics versus topical antiseptics:
We found one systematic review [24] (search date 2005; 1 RCT, [25] 51 adults). The RCT compared three treatments: oral antibiotics, topical antiseptics, and topical antibiotics (see above for full details of preparations). [25] It found no significant difference between oral antibiotics and topical antiseptics in the rate of persistent activity on otoscopy (persistent discharge) at 2 to 4 weeks (8/13 [62%] with oral antibiotics *v* 13/20 [65%] with topical antiseptics; RR 0.95, 95% CI 0.55 to 1.62). The RCT may have been underpowered to detect a clinically important difference.

Systemic antibiotics versus each other:
We found three RCTs. [30] [31] [32] The first RCT found that oral ciprofloxacin (500 mg twice daily) increased the proportion of people with clinical cure compared with co-amoxiclav (amoxicillin–clavulanate; 500 mg 3 times daily) after 10 days' treatment (76 people; AR for resolution of otorrhoea: 24/40 [60.0%] with ciprofloxacin *v* 13/35 [37.1%] with co-amoxiclav; P = 0.04). [30] The second RCT (190 adults) found no significant difference between oral cefotiam hexetil and co-amoxiclav given for 10 days in persistent otoscopic abnormality after the end of treatment (37/94 [39%] with cefotiam *v* 33/94 [35%] with co-amoxiclav; P = 0.55; see comment below). [31] The third RCT (30 adults, 22 analysed) compared oral levofloxacin (500 mg once daily) versus oral co-amoxiclav (675 mg 3 times daily) for 10 days. [32] It found that levofloxacin improved resolution of otorrhoea compared with co-amoxiclav, this improvement was of borderline significance (9/12 [75%] with levofloxacin *v* 6/10 [60%] with co-amoxiclav; P = 0.05).

Systemic antibiotics added to mastoidectomy or tympanoplasty:
We found one RCT (26 adults having mastoidectomy/tympanoplasty), which found that preoperative intravenous ceftazidime (2 g 12 hours preoperatively and 1–2 g 8-hourly for 5 days postoperatively) reduced the proportion of people with otorrhoea on otoscopy or with positive *Pseudomonas aeruginosa* cultures at 2 months compared with no antibiotic (1/14 [7%] with iv ceftazidime *v* 7/12 [58%] with no antibiotic; P = 0.01). [33] Although randomisation was thorough, groups are likely to have been unbalanced for baseline severity, with more people in the antibiotic arm having only tympanoplasty.

Systemic antibiotics versus topical antibiotics plus systemic antibiotics:
See benefits of topical antibiotics plus systemic antibiotics, p 6 .

Harms:

Systemic antibiotics versus placebo:
We found no RCTs.

Systemic antibiotics versus topical antibiotics:
The first RCT found no adverse effects. [25] The second and third RCT found no adverse effects with either topical ciprofloxacin or intramuscular gentamicin and reported that audiometric functioning did not worsen during treatment (no further data reported). [26] [27] The fourth RCT did not report adverse effects. [28] The fifth RCT found no change in audiometric functioning before or after treatment (no further data reported). [29]

Systemic antibiotics versus topical antiseptics:
See harms of topical antiseptics., p 9

Systemic antibiotics versus each other:
The first RCT reported diarrhoea, nausea, abdominal pain, and headache among people taking either oral ciprofloxacin (10% of people) or oral co-amoxiclav (amoxicillin–clavulanate) (14% of people). [30]

The second RCT found that co-amoxiclav significantly increased the frequency of gastrointestinal adverse effects (abdominal pain, diarrhoea, and flatulence) compared with cefotiam (34/95 [36%] with co-amoxiclav *v* 13/95 [14%] with cefotiam; P = 0.001). [31]

The third RCT comparing oral levofloxacin versus oral co-amoxiclav found no adverse effects. [32] None of the RCTs reported changes in hearing as measured by pure tone audiometry.

Systemic antibiotics added to mastoidectomy or tympanoplasty:
The RCT found that there were no adverse effects reported with ceftazidime. [33]

Systemic antibiotics versus topical antibiotics plus systemic antibiotics:
See harms of topical antibiotics plus systemic antibiotics, p 6 .

Comment:

None.

OPTION ANTIBIOTICS (TOPICAL PLUS SYSTEMIC) IN ADULTS

Reduction in otorrhoea

Topical plus systemic antibiotics compared with topical antibiotics alone We don't know whether systemic antibiotics plus topical antibiotics are more effective at reducing ottorrhoea at 2 weeks (very low-quality evidence).

Compared with systemic antibiotics alone We don't know whether topical plus systemic antibiotics are more effective at increasing discharge resolution in adults (low-quality evidence).

Note

We found no direct information from RCTs about whether topical plus systemic antibiotics are better than no active treatment in adults with chronic suppurative otitis media.

For GRADE evaluation of interventions for chronic suppurative otitis media, **see table, p 19 .**

Benefits:

Topical plus systemic antibiotics versus placebo:

We found no systematic review or RCTs comparing topical plus systemic antibiotics versus placebo in adults.

Topical plus systemic antibiotics versus topical antibiotics alone:

We found three RCTs. [26] [34] [35] The first RCT (60 adults) compared three treatments: oral ciprofloxacin, topical ciprofloxacin, and oral plus topical ciprofloxacin. [26] It found no significant difference in otorrhoea at 2 weeks with topical ciprofloxacin with or without oral ciprofloxacin given for 5–10 days (5/20 [25%] with oral plus topical ciprofloxacin *v* 3/20 [15%] with topical ciprofloxacin alone; RR 1.67, 95% CI 0.46 to 6.06). [26] The second RCT (30 adults) found no significant difference in otorrhoea at the end of treatment with topical gentamicin–hydrocortisone (for 4 weeks) with and without oral metronidazole given for 2 weeks (6/14 [43%] with topical gentamicin–hydrocortisone plus oral metronidazole *v* 6/16 [38%] with topical gentamicin–hydrocortisone alone; significance assessment between group not reported). [34] The third RCT (80 adults, 89 ears) compared topical plus oral non-quinolone antibiotics versus topical quinolone antibiotics alone. [35] It found that topical ofloxacin (0.3%) reduced the proportion of ears exhibiting persistent signs (ear pain, discharge, or inflammation on otoscopic examination) after 2 weeks compared with oral amoxicillin plus topical chloramphenicol (33% of ears with topical ofloxacin *v* 63% of ears with oral amoxicillin plus topical chloramphenicol; number of ears examined not reported; $P < 0.001$). The RCT randomised people but analysed the number of ears with persistent otorrhoea.

Topical antibiotics plus systemic antibiotics versus systemic antibiotics alone:

We found two RCTs. [26] [36] The first RCT (60 adults) compared three treatments: topical ciprofloxacin alone (250 µg/mL, 3 drops twice daily), oral ciprofloxacin alone (250 mg twice daily), or topical (250 µg/mL, 3 drops twice daily) plus oral (250 mg twice daily) ciprofloxacin. [26] It found that topical plus oral ciprofloxacin significantly increased discharge resolution compared with oral ciprofloxacin alone (15/20 [75%] with topical ciprofloxacin plus oral ciprofloxacin *v* 8/20 [40%] with oral ciprofloxacin alone; $P < 0.05$). The second RCT (248 adults) compared topical ceftizoxime (2 g/day) versus 0.9% sodium chloride solution among people who were given intramuscular ceftizoxime for 7 days. [36] It found no significant difference at the end of 7 days' treatment between the two groups in terms of improvement of symptoms and otoscopic findings (improvement: 96% with topical plus intramuscular ceftizoxime *v* 93% with topical 0.9% sodium chloride plus intramuscular ceftizoxime; reported as not significant, significance assessment not reported).

Harms:

Topical plus systemic antibiotics versus placebo:

We found no RCTs.

Topical plus systemic antibiotics versus topical antibiotics alone:

The first RCT reported that audiometric functioning did not worsen during treatment and no adverse effects were reported (no further data reported). [26] The second RCT gave no information on adverse effects. [34] The third RCT reported ototoxicity (defined as an elevation in bone conduction thresholds, speech reception thresholds of greater-than or equal to 5 dB, or both) with amoxicillin–chloramphenicol but not with ofloxacin (absolute numbers not reported). [35] See harms of topical antibiotics, p 7 and harms of systemic antibiotics, p 4 .

Topical antibiotics plus systemic antibiotics versus systemic antibiotics alone:

The first RCT reported that "audiometric functioning did not worsen" during treatment and no adverse effects were reported (no further data reported). [26] The second RCT found that a similar proportion of people taking combined treatment and systemic antibiotics had adverse effects (skin rash, diarrhoea, and epigastralgia: 0.8% with combined topical plus systemic antibiotics *v* 1.6% with systemic antibiotics alone; significance assessment not reported). [36]

Comment: The difference in the results of the three RCTs comparing topical plus systemic antibiotics versus topical antibiotics alone may be because of the spectra of antibiotics being compared. When antibiotics of the same class were compared, [26] addition of systemic antibiotics to topical antibiotics did not seem to produce any added benefit. By contrast, a topical quinolone antibiotic was found to be more effective than topical plus oral non-quinolones. [35] This suggests that drugs against gram negative bacteria, particularly *Pseudomonas aeruginosa*, may be particularly effective in reducing otorrhoea. The same might be true regarding the non-benefit of adding topical to systemic antibiotics of the same class. [36]

OPTION ANTIBIOTICS (TOPICAL) IN ADULTS

Reduction in otorrhoea

Compared with placebo Topical ciprofloxacin may be more effective at reducing persistent otorrhoea at 7 days in adults with chronic suppurative otitis media (very low-quality evidence).

Compared with each other Topical quinolones and topical non-quinolones seem equally effective at 1 and at 3 weeks at reducing persistent discharge in adults with suppurative otitis media (high-quality evidence).

Compared with systemic antibiotics Topical antibiotics seem to be more effective at reducing persistent otorrhoea at 1−2 weeks in adults (moderate-quality evidence).

Compared with topical antiseptics We don't know whether topical antibiotics are more effective at reducing persistent activity on otoscopy (persistent discharge) at 2−4 weeks in adults with chronic suppurative otitis media (low-quality evidence).

Compared with topical antibiotics plus systemic antibiotics We don't know whether topical antibiotics are more effective at reducing ottorrhoea at 2 weeks (very low-quality evidence).

Topical antibiotics plus topical corticosteroids compared with placebo Topical antibiotics plus topical corticosteroids (gentamicin plus hydrocortisone) are more effective at reducing otitis media as determined by otoscopy in adults with chronic suppurative otitis media compared with placebo (moderate-quality evidence).

Topical antibiotics added to tympanoplasty compared with no treatment Topical antibiotics added to tympanoplasty seem to be no more effective at closing tympanic perforations in adults about to have tympanoplasty (moderate-quality evidence).

Adverse effects

Vestibular ototoxicity has been associated with Topical non-quinolone antibiotics.

For GRADE evaluation of interventions for chronic suppurative otitis media, **see table, p 19 .**

Benefits:

Topical antibiotics versus placebo:

We found one systematic review (search date 2005), [37] which identified one RCT comparing topical antibiotics alone versus placebo in adults. [26] All participants received ear cleansing. The RCT (50 adults with chronic suppurative otitis media but no cholesteatoma in a hospital clinic in Thailand) found that, after 7 days, topical ciprofloxacin in 0.9% sodium chloride (5 drops 0.25 g/L 3 times daily for 7 days) significantly reduced persistent otorrhoea on otoscopic examination compared with topical 0.9% sodium chloride alone (persistent signs of otorrhoea: 3/19 [16%] with ciprofloxacin *v* 14/16 [88%] with 0.9% sodium chloride; RR 0.18, 95% CI 0.06 to 0.52; NNT 2, 95% CI 2 to 3). [26] The RCT lasted only 7 days, had 30% loss to follow up (15/50), and did not describe the methods of randomisation and allocation concealment clearly.

Topical antibiotics versus each other:

We found one systematic review (search date 2005; 5 RCTs; 428 adults plus 84 ears) [37] which found no significant difference in the rate of persistent discharge between a topical quinolone (ciprofloxacin) and a topical non-quinolone (gentamicin or tobramycin) at 1 week (3 RCTs, 402 adults; 25/193 [13%] with topical quinolones *v* 43/209 [21%] with topical non-quinolones, RR 0.89, 95% CI 0.59 to 1.32). The review also found no significant difference between ciprofloxacin and tobramycin in persistent discharge at 3 weeks (2 RCTs, 77 adults; 14/39 [36%] with ciprofloxacin *v* 14/38 [37%] with tobramycin; RR 0.97, 95% CI 0.54 to 1.72). [37] Two RCTs identified by the review compared different topical non-quinolone antibiotics, and found no significant difference in the proportion of people who still had a wet ear on otoscopy at the end of treatment (8/50 [16%] with topical trimethoprim–sulfacetamide–polymyxin B *v* topical gentamicin 4/50 [8%]; RR 2.00, 95% CI 0.64 to 6.22; [38] and 4/35 [11%] with topical trimethoprim–sulfacetamide–polymyxin B *v* 13/33 [39%] with topical trimethoprim–polymyxin B; RR 0.29, 95% CI 0.11 to 0.80 . [39]

Topical antibiotics versus systemic antibiotics:
See benefits of systemic antibiotics, p 4 .

Topical antibiotics versus topical antiseptics:
We found one systematic review [37] (search date 2005, 2 RCTs). [25] [40] The first RCT identified by the review (75 adults randomised, 51 analysed) compared three treatments: topical antiseptics (boric acid and iodine powder plus ear cleansing under microscopic vision), topical antibiotics (gentamicin or chloramphenicol), and oral antibiotics (cefalexin, flucloxacillin, cloxacillin, or amoxicillin, according to bacterial sensitivity). [25] It found no significant difference between topical antibiotics and topical antiseptics in persistent activity on otoscopy (persistent discharge) at 2 to 4 weeks (15/18 [83%] with topical antibiotics *v* 13/20 [65%] with topical antiseptics; RR 1.28, 95% CI 0.87 to 1.88). [25] The RCT may have been underpowered to detect a clinically important difference between groups. The second RCT identified by the review (51 adults with chronic suppurative otitis media without cholesteatoma in a hospital clinic in Israel; 60 ears) compared three interventions: 3 weeks' treatment with topical ciprofloxacin, topical tobramycin, and dilute antiseptic solution (1% aluminium acetate). [40] It found that ciprofloxacin significantly reduced the proportion of people with unimproved otorrhoea compared with diluted aluminium acetate (4/19 [21%] with ciprofloxacin *v* 10/17 [59%] with diluted aluminium acetate; P = 0.02). The RCT found no significant difference in otorrhoea between tobramycin and diluted aluminium acetate (5/18 [28%] with tobramycin *v* 10/17 [59%] with diluted aluminium acetate; P = 0.06)). This RCT randomised people to treatments, but presented results in terms of number of ears. [40]

Topical antibiotics alone versus topical antibiotics plus systemic antibiotics:
See benefits of topical antibiotics plus systemic antibiotics, p 6 .

Topical antibiotics plus topical corticosteroids:
See benefits of topical antibiotics plus topical corticosteroids, p 3 .

Topical antibiotics added to tympanoplasty:
We found one RCT (101 adults about to have tympanoplasty), which compared preoperative topical ofloxacin instilled for 10 minutes, preoperative topical ofloxacin instilled for 3 minutes, or no preoperative topical treatment. [41] It found no significant difference among groups for closure of tympanic perforations (28/33 [84.8%] with 10 minutes' ofloxacin *v* 27/33 [81.8%] with 3 minutes' ofloxacin *v* 31/35 [88.6%] with no treatment; reported as no significant difference among groups, P value not reported). However, the RCT may have lacked power to detect clinically important differences.

Harms:

Topical antibiotics versus placebo:
The RCT found that audiometric functioning did not worsen during treatment and no adverse effects were reported (no further data reported). [26]

Topical antibiotics versus each other:
The systematic review found that the rates of minor adverse effects reported in RCTs were low and did not vary appreciably among antibiotics. [37] These minor adverse effects included *Candida* infections, dizziness, itching, stinging, and earache. [21] [40] [39]

Topical antibiotics versus systemic antibiotics:
See harms of systemic antibiotics, p 4 .

Topical antibiotics versus topical antiseptics:
See harms of topical antiseptics, p 9 .

Topical antibiotics alone versus topical antibiotics plus systemic antibiotics:
See harms of topical antibiotics plus systemic antibiotics, p 6 .

Topical antibiotics plus topical corticosteroids:
See harms of topical antibiotics plus topical corticosteroids, p 3 .

Topical antibiotics added to tympanoplasty:
The RCT found that there were no major adverse effects reported with topical ofloxacin (no further data reported). [41]

Ototoxic effects of topical antibiotics:
The RCTs identified by the systematic review (7 RCTs in adults and children) [37] and two additional RCTs in adults and children, [42] [43] found negligible or no change in hearing after topical antibiotics (ciprofloxacin or aminoglycoside).

Comment: We identified one abstract describing an RCT (36 adults) comparing topical ciprofloxacin versus topical neomycin–polimixin–fluocinolone (NPF); we were unable to obtain the full text of this Spanish language paper to assess the quality of the study. [44] The abstract reported that the RCT found no significant difference in "good" treatment results (rated as "good", "regular", or "poor") between treatments after 10 days (85% with ciprofloxacin *v* 80% with NPF; P value not reported in abstract). There is consensus that topical antibiotics must be combined with thorough ear cleansing to be effective. We found no evidence about the long term effects of topical antibiotics on complications of chronic suppurative otitis media. The comparative RCTs were small and their quality variable. We found no clear evidence from RCTs of ototoxicity associated with any topical antibiotic. Evidence about ototoxicity is based only on the assessment of audiograms after short-term exposure to antibiotics, and case studies that have reported ototoxicity associated with some topical non-quinolone antibiotics for 7–120 days. [45] [46] [47] Most of the people in the observational studies had vestibular rather than cochlear symptoms, suggesting that the evidence from audiograms and hearing tests may not exclude ototoxicity. Most topical non-quinolone antibiotics have licence restrictions against prolonged use, or use in people with perforation of the ear drum.

OPTION ANTISEPTICS (TOPICAL) IN ADULTS

Reduction in otorrhoea

Compared with topical antibiotics We don't know whether topical antiseptics are more effective at reducing persistent activity on otoscopy (persistent discharge) at 2−4 weeks in adults with chronic suppurative otitis media (low-quality evidence).

Compared with systemic antibiotics Topical antiseptics and oral antibiotics seem to be equally effective at reducing the rate of persistent activity on otoscopy (persistent discharge) at 2−4 weeks in adults (moderate-quality evidence).

Note

We found no direct information from RCTs about whether topical antiseptics are better than no active treatment in adults with chronic suppurative otitis media.

For GRADE evaluation of interventions for chronic suppurative otitis media, see table, p 19 .

Benefits:

Topical antiseptics versus placebo:
We found no systematic review or RCTs comparing topical antiseptics versus placebo in adults with chronic suppurative otitis media.

Topical antiseptics versus topical antibiotics:
See benefits of topical antibiotics versus topical antiseptics, p 7 .

Topical antiseptics versus systemic antibiotics:
See benefits of systemic antibiotics versus topical antiseptics, p 4 .

Harms:

Topical antiseptics versus placebo:
We found no RCTs.

Topical antiseptics versus topical antibiotics:
The review found negligible or no changes in hearing acuity after topical treatment. [37]

Topical antiseptics versus systemic antibiotics:
The review found negligible or no changes in hearing acuity after topical treatment. [37]

Comment: Topical antiseptics include aluminium acetate, borax, boric acid, hydrogen peroxide, and iodine powder. The available evidence from the RCT in adults is insufficient to establish or exclude a clinically important effect from topical antiseptics.

OPTION CORTICOSTEROIDS (TOPICAL) IN ADULTS

Reduction in otorrhoea

Topical corticosteroids plus topical antibiotics compared with placebo Topical corticosteroids plus topical antibiotics (gentamicin plus hydrocortisone) are more effective at reducing otitis media in adults with chronic suppurative otitis media compared with placebo (moderate-quality evidence).

Compared with topical corticosteroids plus topical antibiotics The topical corticosteroid, betamethasone may be less effective at 3 weeks than topical corticosteroids plus topical antibiotics (gentamicin plus hydrocortisone) at reducing the proportion of people with persistent activity on otoscopy (low-quality evidence).

Note

We found no clinically important results from RCTs about the effects of topical corticosteroids compared with placebo or no treatment in adults with chronic suppurative otitis media.

For GRADE evaluation of interventions for chronic suppurative otitis media, see table, p 19 .

Benefits:

Topical corticosteroids versus placebo or no treatment:
We found no systematic review or RCTs.

Topical corticosteroids versus topical antibiotics plus topical corticosteroids:
See benefits of topical antibiotics plus topical corticosteroids, p 3 .

Harms:

Topical corticosteroids versus placebo or no treatment:
We found no systematic review or RCTs.

Topical corticosteroids versus topical antibiotics plus topical corticosteroids:
See harms of topical antibiotics plus topical corticosteroids, p 3 .

Comment: None.

OPTION EAR CLEANSING (AURAL TOILET) IN ADULTS

We found no clinically important results about ear cleansing compared with no treatment in adults with chronic suppurative otitis media.

For GRADE evaluation of interventions for chronic suppurative otitis media, see table, p 19 .

Benefits:

Ear cleansing versus no treatment:
We found no systematic review, RCTs, or observational studies of sufficient quality comparing ear cleansing versus no treatment in adults.

Harms:

Ear cleansing versus no treatment:
We found no RCTs or observational studies.

Comment: Techniques of ear cleansing vary considerably. In western countries, microsuction of the external and middle ear under microscopic control by a trained operator is the standard method of ear cleansing. Microscopic examination of the ear with ear cleansing is an important aspect of diagnosis of persistent otorrhoea. In developing countries, otoscopic examination after dry mopping, ear wicking, and ear irrigation with sterile liquid is considered part of standard treatment.

OPTION TYMPANOPLASTY WITH OR WITHOUT MASTOIDECTOMY IN ADULTS

We found no clinically important results from RCTs about tympanoplasty with or without mastoidectomy compared with no surgery in adults with chronic suppurative otitis media without cholesteatoma.

For GRADE evaluation of interventions for chronic suppurative otitis media, see table, p 19 .

Benefits:

Tympanoplasty with or without mastoidectomy versus no surgery:
We found no systematic review or RCTs (see comment below).

Harms:

Tympanoplasty with or without mastoidectomy versus no surgery:
We found no RCTs.

Comment: We found many retrospective cohort studies. One of these (41 adults with bilateral chronic suppurative otitis media operated on at 1 unit in Italy) compared hearing in ears that had previous tympanoplasty versus hearing in contralateral ears treated without surgery. [48] The hearing in both operated and non-operated ears progressively deteriorated, but the rate of decline was significantly slower in operated ears. Tympanoplasty can be combined with mastoidectomy when the possibility of restoring some functional hearing without jeopardising surgical clearance of the disease exists. Observational studies have found that the success of surgery depends on several factors: age, technical skill of the surgeon, [49] availability of remnant eardrum and ossicles, [50] and type of mastoidectomy performed. The success rate for sealing a tympanic perforation with a graft can be 90–95%. Hearing deficit may be corrected in about 50–70% of operated ears. [51] [52] [53]

QUESTION What are the effects of treatments for chronic suppurative otitis media in children?

OPTION ANTIBIOTICS (SYSTEMIC) IN CHILDREN

Reduction in otorrhoea

Compared with placebo or no treatment Systemic antibiotics are more effective at reducing persistent otorrhoea at 6 months in children with chronic suppurative otitis media (moderate-quality evidence).

Compared with each other We don't know which systemic antibiotic is more effective at reducing otorrhoea in children with chronic suppurative otitis media (low-quality evidence).

Note

We found no clinically important results from RCTs comparing systemic antibiotics with no treatment or with topical antiseptics in the treatment of children with chronic suppurative otitis media.

For GRADE evaluation of chronic suppurative otitis media, **see table, p 19 .**

Benefits:

Systemic antibiotics versus placebo or no antibiotics in children having no other treatment:
We found no systematic review or RCTs investigating the effects of systemic antibiotics in children receiving no other treatment.

Systemic antibiotics versus placebo or no treatment in children having ear cleansing and debridement:
We found one open label RCT (33 children having ear cleansing by suctioning and debridement for 1–2 weeks), which compared three interventions: intravenous mezlocillin, intravenous ceftazidime, and no antibiotic. [54] It found that intravenous antibiotic (mezlocillin or ceftazidime for 3–21 days) significantly reduced persistent otorrhoea detected at otoscopy after 6 months compared with no antibiotic (0/21 [0%] with iv antibiotic *v* 11/12 [92%] with no antibiotic; P < 0.01; see comment below).

Systemic antibiotics versus each other:
We found two RCTs. [54] [55] The first RCT (33 children) found equal rates of otoscopic evidence of otorrhoea in children receiving intravenous mezlocillin and intravenous ceftazidime at the end of treatment (otoscopic evidence of otorrhoea: 0/17 [0%] with mezlocillin *v* 0/19 [0%] with ceftazidime; significance assessment not reported). [54] The second RCT (30 children) found no significant difference in success rates (complete disappearance of discharge: 84.6% with ceftazidime *v* 67.0% with aztreonam; P value reported as not significant) and days to disappearance (7.9 days with ceftazidime *v* 8.4 days with aztreonam) between ceftazidime and aztreonam. [55]

Systemic antibiotics versus topical antibiotics:
See benefits of topical antibiotics, p 11 .

Systemic antibiotics versus topical antiseptics:
We found no systematic review or RCTs.

Harms:

Systemic antibiotics versus placebo or no antibiotics in children having no other treatment:
We found no RCTs.

Systemic antibiotics versus placebo or no treatment in children having ear cleansing and debridement:
The RCT reported no worsening of hearing during or after the systemic antimicrobial treatment as measured by audiometry (figures not reported). [54]

Systemic antibiotics versus each other:
The first RCT reported no worsening of hearing during or after the systemic antimicrobial treatment as measured by audiometry (figures not reported). [54] The second RCT reported that both antibiotics were well tolerated (no further data reported). [55]

Systemic antibiotics versus topical antibiotics:
See harms of topical antibiotics., p 11

Comment:

We found no clear evidence from RCTs that systemic antibiotics differ in their effectiveness. The studies in children found similar results to those in adults.

OPTION ANTIBIOTICS (TOPICAL) IN CHILDREN

Reduction in otorrhoea

Compared with each other We don't know which topical antibiotic is more effective at increasing discharge resolution rates at 2 weeks in children with chronic suppurative otitis media (very low-quality evidence).

Compared with topical antiseptics Topical antibiotics are more effective than topical antiseptics at reducing persistent discharge at 1–4 weeks in children with chronic suppurative otitis media (moderate-quality evidence).

Note
We found no clinically important results from RCTs about topical antibiotics compared with topical antibiotics plus topical corticosteroids in children with chronic suppurative otitis media.

For GRADE evaluation of interventions for chronic suppurative otitis media, see table, p 19 .

Benefits:

Topical antibiotics versus placebo or no treatment:
We found one systematic review (search date 2005), which found no RCTs solely in children. [37]

Topical antibiotics versus each other:
We found one systematic review [37] (search date 2005; which identified one RCT). [56] The RCT (96 children in rural Malawi) compared three treatments given three times daily for 2 weeks: 0.5% neomycin/0.1% polymyxin B, 0.3% ofloxacin, and antiseptic ear drops. Suction cleaning was performed in all groups at the beginning and during the weekly visits. The RCT found no significant difference in discharge resolution rates between neomycin–polimixin and ofloxacin at 2 weeks (54 ears analysed; AR for persistent discharge: 3/14 [21%] with ofloxacin *v* 7/40 [18%] with neomycin–polimixin; RR 1.22, 95% CI 0.37 to 4.10). [56]

Topical antibiotics versus systemic antibiotics:
We found one systematic review (search date 2000), [57] which identified no RCTs solely in children with chronic suppurative otitis media.

Topical antibiotics versus topical antiseptics:
See benefits of topical antiseptics, p 13 .

Topical antibiotics versus topical antibiotics plus topical corticosteroids:
We found no RCTs.

Harms:

Topical antibiotics versus placebo or no treatment:
We found no RCTs.

Topical antibiotics versus each other:
The systematic review [37] and included RCT [56] did not report on adverse effects.

Topical antibiotics versus systemic antibiotics:
We found no RCTs.

Topical antibiotics versus topical antiseptics:
See harms of topical antiseptics., p 13

Topical antibiotics versus topical antibiotics plus topical corticosteroids:
We found no RCTs.

Comment:

We found no RCTs evaluating ototoxicity from any topical antibiotic in children. Evidence about ototoxicity is based only on the assessment of audiograms after short term exposure to the antibiotics, and uncontrolled case studies have reported ototoxicity associated with use of some topical non-quinolone antibiotics for 7–120 days. [58] [59] [60] Most of the people in the observational studies had vestibular rather than cochlear symptoms, suggesting that the evidence from audiograms and hearing tests may not exclude ototoxicity. Most topical non-quinolone antibiotics have licence restrictions against prolonged use or use in people with perforation of the eardrum. See also comment on ear cleansing, p 14 . The RCT identified by the systematic review [37] was published in abstract form and described briefly in a later publication. [61] Details of the methodology were not clearly reported. Follow up was short and sample size was small, suggesting that important differences might not be detected.

OPTION ANTIBIOTICS (TOPICAL) PLUS CORTICOSTEROIDS (TOPICAL) IN CHILDREN

We found no clinically important results from RCTs about topical antibiotics plus topical corticosteroids compared with no active treatment or other treatments in children with chronic suppurative otitis media.

For GRADE evaluation of interventions for chronic suppurative otitis media, see table, p 19 .

Benefits: We found no RCTs comparing topical antibiotics plus topical corticosteroids versus placebo or other treatments.

Harms: We found no RCTs.

Comment: We found no RCTs or systematic reviews about long term effects on complications. See comment on topical antibiotics, p 11 .

OPTION ANTISEPTICS (TOPICAL) IN CHILDREN

Reduction in otorrhoea
Compared with placebo or no treatment Topical antiseptics seem to be no more effective at reducing otorrhoea at 2–6 weeks in children with chronic suppurative otitis media (moderate-quality evidence).

Compared with topical antibiotics Topical antiseptics are less effective at reducing persistent discharge at 1–4 weeks in children with chronic suppurative otitis media (moderate-quality evidence).

For GRADE evaluation of interventions for chronic suppurative otitis media, see table, p 19 .

Benefits:

Topical antiseptics versus placebo or no treatment:
We found no systematic review but found two RCTs. [62] [63] The first RCT (60 children with otorrhoea in a hospital clinic in South Africa, 67 ears) compared aluminium acetate solutions of varying concentrations (13.00% *v* 3.25% *v* 1.30%). [63] The most dilute solution was considered to be inactive. Results were obtained for 56/67 (84%) ears. The RCT found no significant difference in dry ears after 2 weeks (21/26 [81% of ears] with 13% aluminium acetate *v* 15/20 [75%] with 3.25% aluminium acetate *v* 5/10 [50%] with 1.3% aluminium acetate; P = 0.18), however it may have lacked power to detect a clinically significant difference. The second RCT (134 children, 180 ears) compared five interventions: ear cleansing alone, ear cleansing plus topical antiseptic, ear cleansing plus topical antiseptic plus topical antibiotics plus corticosteroid, ear cleansing plus topical antiseptic plus topical antibiotics plus corticosteroid plus oral antibiotic (clindamycin), and no treatment. [62] It found no significant difference between ear cleansing plus topical antiseptic (boric acid 2% in 20% alcohol, 3 drops to each ear, 4 times daily after ear cleansing) and ear cleansing alone in the proportion of children with unchanged otoscopic appearance after 6 weeks (43 children, 58 ears: 12/32 [38%] with topical antiseptic *v* 13/26 [50%] with ear cleansing alone; OR 0.61, 95% CI 0.22 to 1.71). [62]

Topical antiseptics versus topical antibiotics:
We found one systematic review [37] (search date 2005; 3 RCTs). The first RCT (427 African school children) compared topical boric acid (2% in 45% alcohol) versus topical ciprofloxacin (0.3%). [64] The RCT found that topical ciprofloxacin significantly reduced persistent discharge compared with topical boric acid at 4 weeks (66/196 [33.7%] with ciprofloxacin *v* 108/198 [54.5%] with boric acid; RR 0.62, 95% CI 0.49 to 1.78). Topical ciprofloxacin significantly improved hearing compared with topical boric acid at 2 and 4 weeks, although the clinical significance of this improvement was unclear (mean decibel improvement at 2 weeks: 4.32 dB with ciprofloxacin *v* 2.69 dB with boric acid; difference 2.17 dB, 95% CI 0.09 dB to 4.24 dB; P = 0.041; mean decibel improvement at 4 weeks: 5.42 dB with ciprofloxacin *v* 2.63 dB with boric acid; difference 3.43 dB, 95% CI 1.34 dB to 5.52 dB; P = 0.001). However, there was no significant difference in healing of tympanic perforations at 2 and 4 weeks (AR for healing at 2 weeks: 15/207 [7.2%] with ciprofloxacin *v* 14/204 [6.9%] with boric acid; RR 1.06, 95% CI 0.52 to 2.13; AR for healing at 4 weeks: 31/200 [15.5%] with ciprofloxacin *v* 20/199 [10.1%] with boric acid; RR 1.54, 95% CI 0.91 to 2.61). [64] The second RCT identified by the review compared three treatments, given three times daily for 2 weeks: topical antiseptic (2% acetic acid in 25% spirit and 30% glycerin), 0.5% neomycin/0.1% polymyxin B, and 0.3% ofloxacin. Suction cleaning was performed in all groups at the beginning and during the weekly visits. The RCT found that the topical antibiotics significantly reduced persistent discharge compared with topical antiseptic after 2 weeks (96 children randomised, 93 ears in 69 children analysed; AR for persistent discharge: 3/14 [21.4%] with ofloxacin *v* 7/40 [17.5%] with neomycin–polymyxin B *v* 34/39 [87.2%] with topical antiseptic; RR for ofloxacin *v* antiseptic: 0.25, 95% CI 0.09 to 0.68; RR for neomycin–polymyxin B *v* antiseptic: 0.20, 95% CI 0.10 to 0.40). [56] The third RCT identified by the review compared three treatments: a single application of ofloxacin 0.075% in hydroxypropyl methylcellulose (HPMC) 1.5%, povidone iodine 1% in HPMC 1.5%, and HPMC 1.5% alone (placebo), as single applications. It found that topical ofloxacin significantly reduced persistent discharge compared with povidone iodine at 1 week (253 ears; 32/79 [40.5%] with ofloxacin *v* 77/91 [84.6%] with povidone iodine; RR 0.52, 95% CI 0.41 to 0.67). [37]

Topical antiseptics versus topical antibiotic plus corticosteroid:
We found no RCTs.

Topical antiseptics versus systemic antibiotics:
See benefits of systemic antibiotics, p 11 .

Harms:

Topical antiseptics versus placebo or no treatment:
The RCTs gave no information on adverse effects. [62] [63]

Topical antiseptics versus topical antibiotics:
The first RCT identified by the review [37] reported that topical boric acid (antiseptic) increased adverse events (ear pain, irritation, and bleeding on ear mopping combined) compared with topical ciprofloxacin (30/206 [14.6%] with boric acid *v* 17/210 [8.1%] with ciprofloxacin; ARR 6.5%, 95% CI 0.3% to 12.7%). [64] The other two RCTs identified by the review did not report on adverse effects. [37]

Topical antiseptics versus topical antibiotic plus corticosteroid:
We found no RCTs.

Topical antiseptics versus systemic antibiotics:
See harms of systemic antibiotics, p 11 .

Comment:

One RCT enforced allocation concealment and blinded participants, carers, and outcome assessors to the treatment allocated throughout the study. [64] The second RCT is an unpublished study that did not clearly report its methods and had a small sample size. [56] The available evidence suggests that topical antiseptics are less effective than topical antibiotics, particularly quinolones, in the short term resolution of ear discharge. See also comment on ear cleansing, p 14 .

OPTION CORTICOSTEROIDS (TOPICAL) IN CHILDREN

We found no clinically important results from RCTs about topical corticosteroids compared with no active treatment or no treatment in children with chronic suppurative otitis media.

For GRADE evaluation of interventions for chronic suppurative otitis media, see table, p 19 .

Benefits:

Topical corticosteroids versus placebo or no treatment:
We found no systematic review or RCTs.

Harms:

Topical corticosteroids versus placebo or no treatment:
We found no RCTs.

Comment:

None.

OPTION EAR CLEANSING (AURAL TOILET) IN CHILDREN

Reduction in otorrhoea
Compared with no treatment We don't know whether ear cleansing is more effective at drying or healing perforations at 6–16 weeks in children with chronic suppurative otitis media (very low-quality evidence).

For GRADE evaluation of interventions for chronic suppurative otitis media, see table, p 19 .

Benefits:

Ear cleansing versus no treatment:
We found two RCTs. [62] [65] The first RCT (134 children) compared five interventions: ear cleansing alone, ear cleansing plus topical antiseptic, ear cleansing plus topical antiseptic plus topical antibiotics plus corticosteroid (topical dexamethasone 0.05%, framycetin sulphate 0.5%, and gramicidin 0.005%), ear cleansing plus topical antiseptic plus topical antibiotics plus corticosteroid plus oral antibiotic (clindamycin), and no treatment. [62] It found that ear cleansing significantly increased the proportion of improved ears (dry or healed perforations) compared with no treatment after 6 weeks (50% with ear cleansing *v* 18% with no treatment; $P < 0.01$). [62] The second RCT compared three treatments: ear cleansing (dry mopping) alone, ear cleansing (dry mopping) plus topical antibiotics plus systemic antibiotics plus topical corticosteroids, and no treatment. [65] It found no significant difference between ear cleansing and no treatment in resolution of chronic suppurative otitis media (3 arm RCT, 524 children; AR for resolution: 22% with ear cleansing alone *v* 22% with no treatment; difference: +1%, 95% CI –8% to +19%), or in healing of perforated eardrums at 16 weeks (AR: 13% with ear cleansing alone *v* 13% with no treatment; difference: –2%, 95% CI –16% to +12%). The RCTs both had weak methods (see comment below). We found no observational studies of sufficient quality of ear cleansing.

Harms: **Ear cleansing versus no treatment:**
The first RCT did not provide information about adverse effects. [62] The second RCT found no evidence of ototoxicity associated with the treatments and no symptoms or complaints suggesting ototoxicity were noted among its participants. [65]

Comment: Techniques of ear cleansing vary considerably. In some countries, microsuction of the external and middle ear under microscopic control by a trained operator is a standard method of ear cleansing. In other countries, cleansing of the external auditory canal may be performed by parents, carers, or peers by dry mopping with cotton wool on orange sticks about four times daily. Ear cleansing is usually considered as an integral part of any intervention for chronic persistent otorrhoea. Almost all of the RCTs included in this chapter incorporated ear cleansing in the trial arms. The two RCTs that directly compared ear cleansing versus no ear cleansing were performed in areas with a high prevalence of chronic suppurative otitis media (Solomon Islands [62] and Kenya [65]). The first RCT followed all the randomised children for 6 weeks but presented results as number of ears with persistent otorrhoea. [62] It did not describe allocation concealment or blinding methods. The second RCT randomised 145 schools but analysed the numbers of children with persistent otorrhoea. [65] It followed children for 16 weeks, but analysed results only for the 72% of the children who completed the RCT. In this RCT, the randomisation process was concealed, but outcome assessors were not blinded to treatment allocation. [65] Overall, we found no good evidence of benefit from simple ear cleansing alone, but the evidence is not strong enough to exclude a clinically important benefit.

OPTION TYMPANOPLASTY WITH OR WITHOUT MASTOIDECTOMY IN CHILDREN

We found no clinically important results from RCTs about tympanoplasty with or without mastoidectomy compared with no surgery in children with chronic suppurative otitis media without cholesteatoma.

For GRADE evaluation of interventions for chronic suppurative otitis media, **see table, p 19 .**

Benefits: **Tympanoplasty with or without mastoidectomy versus no surgery:**
We found no systematic review or RCTs.

Harms: **Tympanoplasty with or without mastoidectomy versus no surgery:**
We found no RCTs.

Comment: We found no evidence from RCTs, but found numerous retrospective observational studies. Tympanoplasty is often combined with mastoidectomy whenever the possibility of restoring some functional hearing without jeopardising surgical clearance of the disease exists. Observational studies have found that the success of surgery depends on several factors (age, technical skill of the surgeon, [66] presence of middle ear discharge, [67] type of mastoidectomy performed, and technique of middle ear construction [49]). Success rate for sealing a tympanic perforation with a graft can be 90–95%. Hearing deficit may be corrected in about 50–70% of operated ears. [51] [52] [53] Long term prospective follow up of a high risk population (93 Aboriginal children) that received tympanoplasty (6% also received mastoidectomy) found that at median follow up of 103 months after tympanoplasty, 56/93 (60%) had intact tympanic membranes and normal hearing, whereas 17/93 (18%) did not. [68]

GLOSSARY

Cholesteatoma An accumulation of epithelial debris in the middle ear cavity which can arise congenitally or can be acquired. The tissue is probably derived from skin. It grows slowly but can erode and destroy adjacent structures (ossicles, the mastoid, the inner ear, or the bone leading to the intracranial cavity), potentially leading to persistent pain and otorrhoea, hearing loss, dizziness, facial nerve paralysis, and intracranial infection.
Disability Adjusted Life Year (DALY) A measure of the impact of a condition, designed to include the loss attributable to premature death and the loss caused by a disability of known duration and severity. One DALY is equivalent to the loss of 1 year of healthy life.
Ear cleansing Also known as aural toilet, this consists of mechanical removal of ear discharge and other debris from the ear canal and middle ear by mopping with cotton pledgets, wicking with gauze, flushing with sterile solution, or suctioning. This can be done with an otomicroscope or under direct vision with adequate illumination of the middle ear.
Mastoidectomy A general term used to describe various surgical procedures that are usually used to remove abnormal parts of the mastoid bone and surrounding structures, or to allow access to the middle ear.
Tympanoplasty A general term used to describe various surgical repairs of the eardrum or ossicles of the middle ear to improve hearing in people with conductive deafness.
High-quality evidence Further research is very unlikely to change our confidence in the estimate of effect.
Low-quality evidence Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Moderate-quality evidence Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Very low-quality evidence Any estimate of effect is very uncertain.

REFERENCES

1. WHO. Chronic suppurative otitis media. Burden of illness and management options. 2004. http://www.who.int/child-adolescent-health/New_Publications/CHILD_HEALTH/ISBN_92_4_159158_7.pdf (last accessed 8 November 2005).
2. Homoe P. Otitis media in Greenland. Studies on historical, epidemiological, microbiological, and immunological aspects. *Int J Circumpolar Health* 2001;60(suppl 2):1–54.
3. Tos M. Sequelae of secretory otitis media and the relationship to chronic suppurative otitis media. *Ann Otol Rhinol Laryngol* 1990;99:18–19. [PubMed]
4. Daly KA, Hunter LL, Levine SC, et al. Relationships between otitis media sequelae and age. *Laryngoscope* 1998;108:1306–1310.[PubMed]
5. New Zealand Health Technology Assessment Clearing House. *Screening programmes for the detection of otitis media with effusion and conductive hearing loss in pre-school and new entrant school children. A critical appraisal of the literature* (NZHTA report 3). Christchurch, New Zealand, June 1998. Available online at: http://nzhta.chmeds.ac.nz/publications/nzhta3.pdf (last accessed 8 November 2006). Search date 1998; primary sources English language articles in Medline, Cinahl, Healthstar, Current Contents (combined files), Cochrane Library Database of Abstracts of Reviews of Effectiveness, NHS Economic Evaluation Database, New Zealand Bibliographic Network, New Zealand Ministry of Health publications, United States National Institute of Health publications, Catalogues of New Zealand medical libraries, and publications and current projects by the International Network of Agencies for Health Technology Assessment (INAHTA).
6. Verhoeff M, Van der,V, Rovers MM, et al. Chronic suppurative otitis media: A review. *International Journal of Pediatric Otorhinolaryngology* 2006;70:1-12[PubMed]
7. Leach AJ, Morris P.S.. Antibiotics for the prevention of acute and chronic suppurative otitis media in children. . *Cochrane Database of Systematic Reviews 2006, Issue 4.* 2006;Issue 4:-[PubMed]
8. Bastos I. Otitis media and hearing loss among children in developing countries. Malmo: University of Malmo, 1994.
9. Jacob A, Rupa V, Job A, et al. Hearing impairment and otitis media in a rural primary school in south India. *Int J Pediatr Otorhinolaryngol* 1997;39:133–138.[PubMed]
10. Seely DR, Gloyd SS, Wright AD, et al. Hearing loss prevalence and risk factors among Sierra Leonean Children. *Arch Otolaryngol Head Neck Surg* 1995;121:853–858.[PubMed]
11. Antarasena S, Antarasena N, Lekagul S, et al. The epidemiology of deafness in Thailand. *Otolaryngol Head Neck Surg* 1988;3:9–13.
12. Muya EW, Owino O. *Special education in Africa: research abstracts*. Nairobi: UNESCO;1986.
13. Teele DW, Klein JO, Chase C, et al. Otitis media in infancy and intellectual ability, school achievement, speech, and language at age 7 years. Greater Boston Otitis Media Study Group. *J Infect Dis* 1990;162:685–694.[PubMed]
14. Osma U, Cureoglu S, Hosoglu S. The complications of chronic otitis media: report of 93 cases. *J Laryngol Otol* 2000;114:97–100.[PubMed]
15. Kenna M. Incidence and prevalence of complications of otitis media. *Ann Otol Rhinol Laryngol* 1990;99(suppl 149):38–39.
16. Berman S. Otitis media in developing countries. *Pediatrics* 1995;96:126–131.[PubMed]
17. Sorensen H. Antibiotics in suppurative otitis media. *Otolaryngol Clin North Am* 1977;10:45–50.[PubMed]
18. World Health Organization. *Revised global burden of disease (GBD) 2002 estimates.* Available online at: http://www.who.int/healthinfo/bodgbd2002revised/en/index.html (last accessed 9 November 2006).
19. Browning GG, Gatehouse S, Calder IT. Medical management of active chronic otitis media: a controlled study. *J Laryngol Otol* 1988;102:491–495.[PubMed]
20. Picozzi G, Browning G, Calder I. Controlled trial of gentamicin and hydrocortisone ear drops in the treatment of active chronic otitis media. *Clin Otolaryngol* 1983;8:367–368.
21. Crowther JA, Simpson D. Medical treatment of chronic otitis media: steroid or antibiotic with steroid ear-drops? *Clin Otolaryngol* 1991;6:142–144.
22. Kaygusuz I, Karlidag T, Gok U, et al. Efficacy of topical ciprofloxacin and tobramycin in combination with dexamethasone in the treatment of chronic suppurative otitis media. *Kulak Burun Bogaz Ihtisas Dergisi* 2002;9:106–111. [In Turkish][PubMed]
23. Miro N, Perello E, Casamitjana F, et al. Controlled multicenter study on chronic suppurative otitis media treated with topical applications of ciprofloxacin 0.2% solution in single-dose containers or combination of polymyxin B, neomycin, and hydrocortisone suspension. *Otolaryngol Head Neck Surg* 2000;23:617–623.
24. Macfadyen CA, Acuin JM, Gamble C. Systemic antibiotics versus topical treatments for chronically discharging ears with underlying eardrum perforations.. *Cochrane Database of Systematic Reviews* 2006;1:-
25. Browning G, Picozzi G, Calder I, et al. Controlled trial of medical treatment of active chronic otitis media. *BMJ* 1983;287:1024.
26. Esposito S, D'Errico G, Montanaro C. Topical and oral treatment of chronic otitis media with ciprofloxacin. *Arch Otolaryngol Head Neck Surg* 1990;116:557–559.[PubMed]
27. Esposito S, D'Errico G, Mantanaro C. Topical ciprofloxacin vs. intramuscular gentamicin for chronic otitis media. *Arch Otolaryngol Head Neck Surg* 1992;118:842–844.[PubMed]
28. Povedano Rodriguez V, Seco Pinero M, Jurado Ramos A, et al. Efficacy of topical ciprofloxacin in the treatment of chronic otorrhea. *Acta Otorrinolaringol Esp* 1995;46:15–18. [In Spanish][PubMed]
29. Yuen P, Lau S, Chau P, et al. Ofloxacin eardrop treatment for active chronic suppurative otitis media: prospective randomized study. *Am J Otol* 1994;15:670–673.[PubMed]
30. Legent F, Bordure P, Beauvillain C, et al. Controlled prospective study of oral ciprofloxacin versus amoxicillin/clavulanic acid in chronic suppurative otitis media in adults. *Chemotherapy* 1994;40(Suppl 1):16–23.
31. Cannoni M, Bonfils P, Sednaoui P, et al. Cefotiam hexetil versus amoxicillin/clavulanic acid for the treatment of chronic otitis media in adults. *Med Mal Infect* 1997;27:915–921.
32. Gonzalez A, Galindo T. Estudio abierto comparativo del tratamiento de otitis media cronica con levofloxacino vs amoxicillina/clavulanato. *Invest Med Int* 2001;28:33–36. [In Spanish]
33. Lildholdt T, Felding J, Juul A, et al. Efficacy of perioperative ceftazidime in the surgical treatment of chronic otitis media due to *Pseudomonas aeruginosa*. *Arch Otorhinolaryngol* 1986;243:167–169.
34. Picozzi G, Browning G, Calder I. Controlled trial of gentamicin and hydrocortisone ear drops with and without systemic metronidazole in the treatment of active chronic otitis media. *Clin Otolaryngol* 1984;9:305.
35. Supiyaphun P, Kerekhanjanarong V, Koranasophonepun J, et al. Comparison of ofloxacin otic solution with oral amoxycillin plus chloramphenicol ear drop in treatment of chronic suppurative otitis media with acute exacerbation. *J Med Assoc Thai* 2000;83:61–68.[PubMed]
36. Mira E, Benazzo M. Uso topico delle cefalosporine nel trattamento delle otiti medie purulente: valutazione della ceftizoxima (Eposerin). *Riv Ital Otorinolaringol Audiol Foniat* 1992;12:219–225.
37. Macfadyen CA, Acuin JM, Gamble C. Topical antibiotics without steroids for chronically discharging ears with underlying eardrum perforations. In: The Cochrane Library, Issue 4, 2005. Chichester, UK: John Wiley & Sons, Ltd. Search date 2005; primary sources Cochrane Ear, Nose and Throat Disorders Group Trials Register, the Cochrane Central Register of Controlled Trials, Central, The Cochrane Library, Medline, Embase, Lilacs, Amed, Cinahl, Oldmedline, Premedline, metaRegister of Controlled Trials (mRCT), and article references.[PubMed]
38. Gyde MC, Randall RF. Comparative double-blind study of trimethoprim sulfacetamide polymyxin B and of gentamicin in the treatment of otorrhoea. *Ann Otolaryngol Chir Cervicofac* 1978;95:43–55.[PubMed]
39. Gyde M. A double-blind comparative study of trimethoprim polymyxin B versus trimethoprim sulfacetamide polymyxin B otic solutions in the treatment of otorrhea. *J Laryngol Otol* 1981;95:251–259.[PubMed]
40. Fradis M, Brodsky A, Ben David J, et al. Chronic otitis media treated topically with ciprofloxacin or tobramycin. *Arch Otolaryngol Head Neck Surg* 1997;123:1057–1060.[PubMed]
41. Tong MC, Yue V, Ku PK, et al. Preoperative topical ofloxacin solution for tympanoplasty: a randomized, controlled study. *Otol Neurotol* 2002;23:18–20.[PubMed]
42. Ozagar A, Koc A, Ciprut A, et al. Effects of topical otic preparations on hearing in chronic otitis media. *Otolaryngol Head Neck Surg* 1997;117:405–408.[PubMed]
43. De Miguel Martinez I, Vasallo M Jr, Ramos MA. Antimicrobial therapy in chronic suppurative otitis media. *Acta Otorrinolaringol Esp* 1999;50:15–19.[PubMed]
44. Lazo Sáenz GJ, Alonzo Rojo SE, Pérez Blanco A. Topical treatment in chronic otitis media. *An Otorrinolaringol Mex* 1999;45:17–19. [In Spanish]
45. Marias J, Rutka JA. Ototoxicity and topical eardrops. *Clin Otolaryngol* 1998;23:360–367.[PubMed]
46. Leliever WC. Topical gentamicin-induced positional vertigo. *Otolaryngol Head Neck Surg* 1985;93:553–555.[PubMed]
47. Longridge NS. Topical gentamicin vestibular toxicity. *J Otolaryngol* 1994;23:444–446.[PubMed]
48. Colletti V, Fiorino FG, Indelicato T. Surgery vs natural course of chronic otitis media. Long term hearing evaluation. *Acta Otolaryngol* 1991;111:762–768.[PubMed]
49. Soldati D, Mudry A. Cholesteatoma in children: techniques and results. *Int J Pediatr Otorhinolaryngol* 2000;52:269–276.[PubMed]
50. Chang CC, Chen MK. Canal-wall-down tympanoplasty with mastoidectomy for advanced cholesteatoma. *J Otolaryngol* 2000;29:270–273.[PubMed]
51. Vartiainen E, Kansanen M. Tympanomastoidectomy for chronic otitis media without cholesteatoma. *Otolaryngol Head Neck Surg* 1992;106:230–234.[PubMed]
52. Mishiro Y, Sakagami M, Takahashi Y, et al. Tympanoplasty with and without mastoidectomy for non-cholesteatomatous chronic otitis media. *Eur Arch Otorhinolaryngol* 2001;258:13–15.[PubMed]
53. Berenholz LP, Rizer FM, Burkey JM, et al. Ossiculoplasty in canal wall down mastoidectomy. *Otolaryngol Head Neck Surg* 2000;123:30–33.
54. Fliss D, Dagan R, Houri Z, et al. Medical management of chronic suppurative otitis media without cholesteatoma in children. *J Pediatr* 1990;116:991–996.[PubMed]
55. Somekh E, Cordova Z. Ceftazidime versus aztreonam in the treatment of pseudomonal chronic suppurative otitis media in children. *Scand J Infect Dis* 2000;32:197–199.[PubMed]
56. Van Hasselt P. Treatment of chronic suppurative otitis media with suction cleaning and antiseptic versus antibiotic ear drops. Internal Report of Christian Blind Mission International: Bensheim, Germany, 1997.
57. Abes G, Espallardo N, Tong M, et al. A systematic review of the effectiveness of ofloxacin otic solution for the treatment of suppurative otitis media. *ORL J Otorhinolaryngol Relat Spec* 2003;65:106–116. Search date 2000; primary sources Medline, Cochrane Library, Centerwatch Clinical Trial Listing Service, Trial Banks, Research and Researcher Registry: Queen's University, hand searches of collaborators' local libraries, and references lists of retrieved articles.[PubMed]

58. Marias J, Rutka JA. Ototoxicity and topical eardrops. *Clin Otolaryngol* 1998;23:360–367.[PubMed]
59. Leliever WC. Topical gentamicin-induced positional vertigo. *Otolaryngol Head Neck Surg* 1985;93:553–555.[PubMed]
60. Longridge NS. Topical gentamicin vestibular toxicity. *J Otolaryngol* 1994;23:444–446.[PubMed]
61. van Hasselt P, van Kregten E. Treatment of chronic suppurative otitis media with ofloxacin in hydroxypropyl methylcellulose ear drops: a clinical/bacteriological study in a rural area of Malawi. *Int J Pediatr Otorhinolaryngol* 2002;63:49–56.[PubMed]
62. Eason R, Harding F, Nicholson R, et al. Chronic suppurative otitis media in the Solomon Islands: a prospective microbiological, audiometric and therapeutic survey. *N Z Med J* 1986;99:812–815.[PubMed]
63. Thorp MA, Gardiner IB, Prescott CA. Burow's solution in the treatment of active mucosal chronic suppurative otitis media: determining an effective dilution. *J Laryngol Otol* 2000;114:432–436.[PubMed]
64. Macfadyen C, Gamble C, Garner P, et al. Topical quinolone vs. antiseptic for treating chronic suppurative otitis media: a randomized controlled trial. *Trop Med Int Health* 2005;10:190–197.[PubMed]
65. Smith A, Hatcher J, Mackenzie I, et al. Randomised controlled trial of treatment of chronic suppurative otitis media in Kenyan schoolchildren. *Lancet* 1996;348:1128–1133.[PubMed]
66. Darrouzet V, Duclos JY, Portmann D, et al. Preference for the closed technique in the management of cholesteatoma of the middle ear in children: a retrospective study of 215 consecutive patients treated over 10 years. *Am J Otol* 2000;21:474–481.[PubMed]
67. Tos M, Stangerup SE, Orntoft S. Reasons for reperforation after tympanoplasty in children. *Acta Otolaryngol Suppl* 2000;543:143–146.[PubMed]
68. Mak DB, MacKendrick A, Bulsara MK, et al. Long-term outcomes of middle-ear surgery in Aboriginal children. *Med J Aust* 2003;179:324–325.[PubMed]

Jose Acuin
Associate Professor
De La Salle University
Health Sciences Campus
Dasmarinas Cavite
Philippines

Competing interests: None declared.

Disclaimer

The information contained in this publication is intended for medical professionals. Categories presented in Clinical Evidence indicate a judgement about the strength of the evidence available to our contributors prior to publication and the relevant importance of benefit and harms. We rely on our contributors to confirm the accuracy of the information presented and to adhere to describe accepted practices. Readers should be aware that professionals in the field may have different opinions. Because of this and regular advances in medical research we strongly recommend that readers' independently verify specified treatments and drugs including manufacturers' guidance. Also, the categories do not indicate whether a particular treatment is generally appropriate or whether it is suitable for a particular individual. Ultimately it is the readers' responsibility to make their own professional judgements, so to appropriately advise and treat their patients. To the fullest extent permitted by law, BMJ Publishing Group Limited and its editors are not responsible for any losses, injury or damage caused to any person or property (including under contract, by negligence, products liability or otherwise) whether they be direct or indirect, special, incidental or consequential, resulting from the application of the information in this publication.

TABLE 1 **RCTs of topical antibiotics plus topical corticosteroids versus topical antibiotics alone(see text, p 9).**

Ref	Population with CSOM	Comparison	Results
[22] †	80 adults, aged 18–60 years, 103 ears, Turkey	Topical ciprofloxacin *v* topical tobramycin *v* topical ciprofloxacin + dexamethasone *v* topical tobramycin + dexamethasone	Clinical response: 80% with topical ciprofloxacin *v* 70% with topical tobramycin *v* 90% with topical ciprofloxacin + dexamethasone *v* 75% with topical tobramycin + dexamethasone; P greater than 0.03
[23]	322 adults, aged 14–71 years, Spain, 6–12 days' treatment	Topical polymyxin B–neomycin–hydrocortisone *v* topical ciprofloxacin	Cure rates: 117/154 [76%] with topical polymyxin B–neomycin–hydrocortisone *v* 146/168 [87%] with topical ciprofloxacin; difference −11%, 90% CI −16.43% to −5.21% (ITT)

† Limited data available from the English language abstract of this RCT, definition of clinical response not reported in the abstract. CSOM, chronic suppurative otitis media; ITT, intention to treat analysis; Ref, reference.

TABLE 2 **Systematic review of RCTs of systemic antibiotics versus topical antibiotics (see text, p 9).** [24]

RCT	Population with CSOM	Comparison	Persistent otorrhoea
[25]	51 adults Scottish hospital clinic	Various systemic antibiotics (cefalexin, flucloxacillin, cloxacillin, or amoxicillin) *v* topical gentamicin or chloramphenicol	At 4 weeks: 8/13 [62%] with systemic antibiotic *v* 15/18 [83%] with topical antibiotic; RR 0.74, 95% CI 0.46 to 1.19
[26]	60 adults 5–10 days' treatment	Oral ciprofloxacin *v* topical ciprofloxacin	At 1−2 weeks: 12/20 [60%] with oral ciprofloxacin *v* 3/20 [15%] with topical ciprofloxacin; RR 4.00, 95% CI 1.33 to 12.05
[27]	60 adults 5–10 days' treatment	Topical ciprofloxacin *v* im gentamicin	At 1−2 weeks: 17/30 [57%] with im gentamicin with topical ciprofloxacin *v* 5/30 [17%]; RR 3.40, 95% CI 1.44 to 8.03
[28]	60 adults 10 days' treatment	Oral ciprofloxacin *v* topical ciprofloxacin	At 1−2 weeks:15/30 [50%] with oral ciprofloxacin *v* 5/30 [17%] with topical ciprofloxacin; RR 3.00, 95% CI 1.25 to 7.21
[29]	60 adults 7 days' treatment	Oral co-amoxiclav (amoxicillin–clavulanate) *v* topical ofloxacin	At 1−2 weeks: 20/27 (74%) with oral co-amoxiclav *v* 7/29 (24%) with topical ofloxacin; RR 3.07, 95% CI 1.55 to 6.07

CSOM, chronic suppurative otitis media; im, intramuscular; Ref, reference.

TABLE **GRADE evaluation of interventions for chronic suppurative otitis media**

Important outcomes	Reduction in otorrhoea, adverse effects								
Number of studies (participants)	**Outcome**	**Comparison**	**Type of evidence**	**Quality**	**Consistency**	**Directness**	**Effect size**	**GRADE**	**Comment**
What are the effects of treatments for chronic suppurative otitis media in adults?									
2 (154) [19] [20]	Reduction in otorrhoea	Topical antibiotics plus topical corticosteroids *v* placebo	4	–1	0	–1	0	Low	Quality point deducted for sparse data. Directness point deducted for uncertainty about benefit
1 (64) [21]	Reduction in otorrhoea	Topical antibiotics plus topical corticosteroids *v* topical corticosteroids alone	4	–3	0	0	+1	Low	Quality points deducted for sparse data, no intention-to-treat analysis, and uncertainty about blinding. Effect size point added for RR less than 0.5
2 (402) [22] [23]	Reduction in otorrhoea	Topical antibiotics plus topical corticosteroids *v* topical antibiotics alone	4	–1	0	–1	0	Low	Quality point deducted for incomplete reporting of results. Directness point deducted for uncertainty about definition of outcome
5 (247) [25] [26] [27] [28] [29]	Reduction in otorrhoea	Systemic antibiotics *v* topical antibiotics	4	0	0	–1	0	Moderate	Directness point deducted for wide range of comparators
1 (51) [25]	Reduction in otorrhoea	Systemic antibiotics *v* topical antiseptics	4	–1	0	0	0	Moderate	Quality point deducted for sparse data
3 (286) [30] [31] [32]	Reduction in otorrhoea	Systemic antibiotics *v* each other	4	0	–1	0	0	Moderate	Consistency point deducted for conflicting results
1 (26) [33]	Reduction in otorrhoea	Systemic antibiotics added to mastoidectomy or tympanoplasty *v* no antibiotic	4	–1	0	–1	0	Low	Quality point deducted for sparse data. Directness point deducted for baseline differences in disease severity
3 (150) [26] [34] [35]	Reduction in otorrhoea	Topical plus systemic antibiotics *v* topical antibiotics alone	4	–1	–1	–1	0	Very low	Quality point deducted for sparse data. Consistency point deducted for conflicting results. Directness point deducted for wide range of comparators
2 (308) [26] [36]	Reduction in otorrhoea	Topical plus systemic antibiotics *v* systemic antibiotics alone	4	–1	–1	0	0	Low	Quality point deducted for incomplete reporting of results. Consistency point deducted for conflicting results
1 (35) [26]	Reduction in otorrhoea	Topical antibiotics *v* placebo	4	–3	0	0	0	Very low	Quality points deducted for sparse data and methodological issues (poor follow-up, and uncertainty about randomisation and blinding)
5 (570) [37]	Reduction in otorrhoea	Topical antibiotics *v* each other	4	0	0	0	0	High	
2 (89) [25] [40]	Reduction in otorrhoea	Topical antibiotics *v* topical antiseptics	4	–1	–1	0	0	Low	Quality points deducted for sparse data. Consistency point deducted for conflicting results
1 (101) [41]	Reduction in otorrhoea	Topical antibiotics added to tympanoplasty *v* no treatment	4	–1	0	0	0	Moderate	Quality point deducted for sparse data
What are the effects of treatments for chronic suppurative otitis media in children?									
1 (33) [54]	Reduction in otorrhoea	Systemic antibiotics *v* placebo or no treatment in children having ear cleansing and debridement	4	–1	0	0	0	Moderate	Quality point deducted for sparse data

Important outcomes	**Reduction in otorrhoea, adverse effects**								
Number of studies (participants)	**Outcome**	**Comparison**	**Type of evidence**	**Quality**	**Consistency**	**Directness**	**Effect size**	**GRADE**	**Comment**
2 (63) [54] [55]	Reduction in otorrhoea	Systemic antibiotics *v* each other	4	–2	0	0	0	Low	Quality points deducted for sparse data and incomplete reporting of results
1 (96) [56]	Reduction in otorrhoea	Topical antibiotics *v* each other	4	–3	0	0	0	Very low	Quality points deducted for sparse data and methodological issues (uncertainity about methodolody and short follow-up)
2 (103) [62] [63]	Reduction in otorrhoea	Topical antiseptics *v* placebo or no treatment	4	–1	0	0	0	Moderate	Quality point deducted for sparse data
3 (666) [64] [56]	Reduction in otorrhoea	Topical antiseptics *v* topical antibiotics	4	–1	0	0	0	Moderate	Quality point deducted for uncertainty about methodology in one study
2 (658) [62] [65]	Reduction in otorrhoea	Ear cleansing *v* no treatment	4	–2	–1	0	0	Very low	Quality points deducted for allocation and blinding flaws. Consistency point deducted for conflicting results

Type of evidence: 4 = RCT; 2 = Observational;
Consistency: similarity of results across studies.
Directness: generalisability of population or outcomes.
Effect size: based on relative risk or odds ratio.